



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/529,000 | 03/24/2005 | Noriyuki Sato | 0020-5360PUS1 | 4504 |
| 2292 7590 03/11/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 | | | | |
| EXAMINER | | | | |
| LI QIAN JANICE | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1633 | | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 03/11/2009 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/529,000

Applicant(s)

SATO ET AL.

Examiner

Q. JANICE LI

Art Unit

1633

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 6, 7, 12, 14, 19, 20, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 1, 12 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 4, 6, 7, 19, 20, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-849)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The amendment, remarks, and supplemental amendment filed 1/5/09 and 1/30/09 are acknowledged. Claims 1, 2, 12, 14, 19 have been amended. Claims 3, 5, 8-11, 13, 15-18, 21-24, 27 have been canceled. Claims 1, 2, 4, 6, 7, 12, 14, 19, 20, 25, 26 are pending.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-7, 19 and 20, drawn to SEQ ID No: 2, and species election drawn to SEQ ID No: 6 is acknowledged. The traversal is on the ground(s) that SEQ ID Nos: 6-36 are subsequences of SEQ ID No: 2, hence, the subsequences are species. Also claims 25 and 26 depend from claims 19 and 20. The arguments are persuasive. Accordingly, SEQ ID Nos: 2 and 6 will be examined together. Claims 7-36 will be rejoined upon allowance of the generic claims.

Claims 1-26 are pending, however, claims 8-18, 21-24 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 1-7, 19, 20, 25 and 26 are under current examination.

The amended claims 1, 12, 14 are directed to a method of using the peptide of SEQ ID No: 2, and are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim.

Claims 2, 4, 6, 7, 19, 20, 25, 26 are under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. New grounds of rejections are necessitated in view of the amendment.

Claim Objections

Claim 2 is objected to because of the following informalities: claim 2 recites "a peptide...is a partial peptide of a protein". The following phrases are suggested to replace "a partial peptide", i.e. "a fragment of a protein" or "a partial amino acid sequence of a protein". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4, 6, 7, 19, 20, 25, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Konya et al* (J Gen Virol 1997;78:2615-20), in view of *Boeckle et al* (Virol 2002;293:103-117, IDS) and *Kubo et al* (J Immunol 1994;152:3913-24).

The claims are directed to a peptide comprising 8-14 contiguous residues of instant SEQ ID No: 2, wherein the amino acid residue at position 2 of the peptide is specified so that the peptide can bind to a HLA antigen in A24- or B55-restricted manner.

Konya teaches methods for identifying CTL epitopes from the HPV-16 E2 protein for developing HPV-16 associated cancer vaccine, wherein many small peptides between 8-11 amino acids long were found to contain HLA binding motif and have CTL-

inducing activity (i.e. can be recognized by CTL, e.g. the abstract, table 1, figure 1).

Konya does not teach developing a vaccine for HPV-8.

Boeckle supplemented *Konya* by establishing it was well known in the art that HPV-8 induces benign epithelial tumors of the skin, which may progress to skin carcinoma (e.g. the Introduction, page 103), hence one skilled in the art would have motivated to develop vaccines for HPV-8 associated tumor and antigenic proteins of HPV-8 would be the subject of investigation for developing HPV-8 vaccine.

Boeckle also supplemented *Konya* by establishing the coding nucleic acid and amino acid sequence (=instant SEQ ID No: 2) of HPV-8 E2 protein were well known in the art at the time before instant filing (see figure 1). Although the interest of *Boeckle* was not developing vaccine for HPV-8 associated cancer, but rather regulating viral gene expression, thus E2 binding protein, it would have been obvious for those skilled in the art intending to developing a HPV-8 vaccine to start from E2 protein of HPV-8 since E2 protein of HPV-16 is a strong immunogenic protein as taught by *Konya*. Here, both the sequence of HPV-8 E2 protein and the method of screening for CTL-epitope were available in the art, any work associated with the design and search would be considered routine experimentation.

The combined teaching of *Konya* in view of *Boeckle* does not mention motifs required for CTL-inducing peptides so that they bind specifically to HLA-A24 or HLA-B55 antigen.

Kubo remedies the deficiency by establishing the missing element in *Konya* in view of *Boeckle* was well known in the art at the time of instant filing date. *Kubo* teaches

Art Unit: 1633

that most CTLs recognize foreign antigen in association with class I molecules (HLA alleles) in the form of a peptide fragment bound to the MHC class I molecule, wherein the peptides generally comprise 8-10 residues, the binding motif of the peptides for different alleles is allele-specific and well characterized. For example, *Kubo* teaches peptides that specifically bind HLA-A24 displayed anchor residues predicted by a specific motif at position 2 and at the COOH-terminal, regardless of peptide length, and synthetic versions of the naturally processed peptides were shown to bind to the appropriate alleles. *Kubo* teaches the knowledge provides a rational approach to search peptides with epitopes restricted to binding of certain HLA alleles for clinical use (e.g. the abstract, table V).

Accordingly, it would have been *prima facie* obvious to the skilled in the art intending to develop a vaccine for HPV-8 to apply the method taught by *Konya* by identifying CTL epitopes within or start from the E2 protein of HPV-8 as disclosed by *Boeckle* with a reasonable expectation of success. It would also have been *prima facie* obvious to the skilled in the art to design a given peptide of interest for binding to a specific HLA allele of interest with a corresponding HLA allelic binding motif. The ordinary skilled artisan would have been motivated to do so for promoting a desired CTL response in the HPV-8 vaccine development. Given the knowledge in the art as taught by the combined teachings, one would have had a reasonable success in searching and modifying fragments of SEQ ID No: 2 for developing a HPV-8 vaccine. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. JANICE LI** whose telephone number is **571-272-0730**. The examiner can normally be reached on 9 AM -7:00pm, Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Weitach** can be reached on **571-272-0739**. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

*/Q. JANICE LI/
Primary Examiner, Art Unit 1633*

